

**REMARKS**

Claims 1-34 were pending in the present application. Claims 26-34 were previously withdrawn from consideration as drawn to a non-elected invention. By virtue of this response, claim 9 has been cancelled, claims 1 and 8 have been amended, and no new claims have been added. Support for these amendments may be found throughout the Specification, and particularly in paragraphs 22, 62, and figures 5-8. Accordingly, claims 1-8 and 10-25 are currently under consideration.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

***Priority***

The Office Action indicates that the current status of all nonprovisional parent applications referenced should be included. The Applicant has amended the first page of the specification to reflect that the parent application in this case (U.S. Patent Application Serial No. 09/881,862, filed on June 14, 2001) has issued as U.S. Patent Number 6,722,360.

***Oath/Declaration***

The Office Action states that the oath/declaration is defective because non-initialed and/or non-dated alterations have been made to the oath or declaration. Filed herewith is a replacement declaration executed by the Inventor. This replacement declaration cures the deficiencies of the original declaration objected to by the Office Action. In particular, the replacement declaration identifies the application by application number and filing date, and does not include any non-initialed or dated alternations.

***Claim Rejection Under 35 U.S.C. § 102(b)***

Claims 1-10, and 12-25 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by US 4,601,465 to Roy ("Roy"). The Applicant respectfully disagrees. Independent

claim 1 (from which claims 2-7 depend), independent claim 8 (from which claims 9-19 depend), independent claim 20 (from which claims 21-23 depend), and independent claim 24 (from which claim 25 depends) all include features that are neither shown nor described in Roy. A reference must disclose a device having *all* features of a claimed device in order to anticipate a claim. MPEP §2131. The pending application shows and describes devices that *fit substantially within a patient's mouth* (oral cavity). In contrast, Roy shows devices that do not fit substantially within a mouth, but extends out of the mouth for a significant distance because they include a long tubular body specifically to project from the mouth, at the end of which is located a valve. Each of the independent claims and associated dependent claims are considered in more detail below.

#### *Claims 1-7*

Independent claim 1 recites a device that *fits substantially within a patient's mouth*. Roy does not show or describe a device that fits *substantially within* a patient's mouth. Only a small region of Roy's device (the mouthpiece) fits within a user's mouth. Roy's device has an elongated body that extends from a user's mouth. Although Roy's device can be connected to a mouthpiece, the mouthpiece is located at one end of the long tubular body of Roy's device. See, e.g., Roy's abstract ("A tubular body defining an air duct is connected at one end to the mouth-piece or to the mask with the air duct in alignment and communication with the opening."). See also, Roy, col. 2, lines 1-6. The long tubular body projects from the user's face. See Roy, figs. 1, 5, and 7. Thus Roy's device does not fit substantially within a patient's mouth since the majority of the device (e.g., the body of the device) projects from the user's face.

Roy also emphasizes that it is important that the device includes this long tubular body. According to Roy: "A very important advantage of the device according to the invention is that the dead space provided by the passages and ducts 3, 5, 7 or 32 between the mouth-piece 9 or mask 43 and the obstruction means 17 and 33, substantially increases the dead respiratory volume of the user." Roy, col. 6, lines 42-54. See also, Roy's abstract, "Proper stimulation is obtained when use is made of a tubular body long enough to increase the dead space of the respiratory system of the person using the device."

Since Roy's device is not configured *to fit substantially within a patient's mouth* as recited by claims 1-7, Roy does not anticipate claims 1-7. The 35 U.S.C. §102(b) rejection of claims 1-7 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 1-7.

#### *Claims 8-19*

Independent claim 8 recites a device comprising a body configured to *fit substantially within a patient's mouth*. As described above, Roy does not show or describe a device that fits *substantially within* a patient's mouth, as recited in the claims. The devices described by Roy are instead configured to project from the user's face. In particular, Roy's device has a long tubular body that projects from the subject's mouth or face.

Since Roy does not show or describe a device that is configured to fit substantially within a patient's mouth, Roy cannot anticipate claims 8-19. The 35 U.S.C. §102(b) rejection of claims 8-19 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 8-19.

#### *Claims 20-23*

Independent claim 20 recites a housing configured to be held in a patient's mouth, the housing enclosing at least one valve. Roy does not show or describe a valve enclosed by a housing configured to be held in a patient's mouth. Roy's check-valve is not enclosed by a housing configured to be held in a patient's mouth, because Roy's valve is separated from a mouthpiece by a passage or duct, creating a dead space between the mouthpiece and the valve. See Roy, Abstract ("A tubular body defining an air duct is connected at one end to the mouth-piece or to the mask with the air duct in alignment and communication with the opening. The device also comprises a membrane mounted in the tubular body *at the other end thereof*," emphasis added).

Thus, Roy cannot anticipate claims 20-23. The 35 U.S.C. §102(b) rejection of claims 20-23 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 20-23.

*Claim 24 and 25*

Independent claim 24 recites a means *on a mouthpiece* for causing an air flow resistance to expiration that is greater than an air flow resistance to inspiration. As already described above, Roy does not show or describe a means *on a mouthpiece* for causing an air flow resistance to expiration that is greater than an air flow resistance to inspiration.

Roy's obstruction means is not on a mouthpiece. Instead, Roy's obstruction means is separated from the mouthpiece by passages or ducts within the tubular body (creating a dead space). Thus, Roy cannot anticipate claims 24 and 25. The 35 U.S.C. §102(b) rejection of claims 24 and 25 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 24 and 25.

***Claim Rejection Under 35 U.S.C. § 103(a)***

*Claim 11*

Claim 11 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Roy. According to the Office Action:

“As to Claim 11, Roy teaches essentially all of the limitations except fro wherein the body comprises at least one concave channel configured to receive a patient's teeth. Roy, rather teaches elements 15 as shown in Figure 1 to bite onto by a patient's teeth. One of ordinary skill in the art at the time of the invention would expect Roy's device to work equally as well as the Applicant's device since both would perform the function of retaining the device in the patient's mouth.” Office Action of April 5, 2005, page 7.

The Applicant respectfully disagrees. As described above, Roy does not describe all of the features of claim 8, from which claim 11 depends. In particular, Roy does not show or describe a

valve device that is *configured to fit substantially within a patient's mouth*, as recited by the claims. Furthermore, even modifying element 15 of Roy to describe a concave channel cannot cure this deficiency. In order to establish obviousness, a reference (of combination of references) must teach or suggest all the features of the claim. MPEP §2142.

In this case, not only is Roy missing a feature recited in the claims, but Roy explicitly teaches away from including this feature. As described above, Roy describes an elongated body (resulting in increased “dead space”) as a “very important advantage.” Roy, col. 6, lines 42-54. The bulk of Roy's device (the elongated tubular body) is not held within the subject's mouth, but projects from the subject's mouth.

Thus, claim 11 cannot be obvious from Roy, because Roy does not teach or suggest all of the features of the claim. The 35 U.S.C. §103(a) rejection of claim 11 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection of claim 11.

### ***Double Patenting***

#### ***Claim 24***

Claim 24 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,722,360.

Applicant will reply to this rejection when allowable subject matter has been indicated. Until then, the Applicant has no way of knowing whether a rejection under judicial double patenting is proper or whether submission of a terminal disclaimer under 37 C.F.R. §1.321 would be appropriate.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, the Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **578632000201**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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